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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,810

09/12/2006

Adrian Brown

PU60746

1607

20462 7590 07/22/2010  
GlaxoSmithKline  
GLOBAL PATENTS -US, UW2220  
P. O. BOX 1539  
KING OF PRUSSIA, PA 19406-0939

EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

07/22/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,810	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/12/06;10/19/07;04/23/10</u>                                 | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the Application**

Receipt is acknowledged of the Response to Restriction/Election requirement filed 04/23/10 and the Information Disclosure Statements (IDS) filed 09/12/06, 10/19/07 and 04/23/10.

Applicant's election without traverse of Group III (claims 47-52) and Election of Species - Formulation #4 (from claim 84) in the reply filed on 23 April 2010 is acknowledged.

Claims 47-84 are pending in this action. New claims 53-84 have been added. Claims 1-46 have been cancelled. Claims 47-84 have been examined in this action. Claims 47-84 are rejected.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 09/12/06, 10/19/07 and 04/23/10 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

\* \* \* \* \*

### ***Claim Objections***

Claims 63 and 84 are objected to because of the following informalities: In claim 63, the semi-colon (;) after the term "cellulose acetate phthalate" is misplaced and should be replaced with a comma (,). In claim 84, after the terms "which is", the claim should be provided with proper Markush terminology, i.e., "selected from the group consisting of". Appropriate correction is required.

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\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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**Claims 47-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit *et al* (hereinafter “Petereit”) (U.S. Pat. Appln. Pubn. No. 2002/0160042) in view of McAllister *et al*. (hereinafter “McAllister”) (U.S. Pat. Appln. Pubn. No. 2003/0068369).**

**Petereit ('042)** teaches a process for producing moldings by injection-molding and injection-molded capsules made thereby, which comprise methacrylate copolymers composed of from 50% to 70% by weight of methyl acrylate, 10 to 30% by weight of methyl methacrylate, and 5% to 15% by weight of methacrylic acid (see abstract, ¶ 0005-0030 & 0038 & Example 1). The capsule may include other components, such as a release agent, a plasticizer, additives or auxiliaries, pharmaceutical agents, and other polymers or copolymers (see abstract). Plasticizers such as triethyl citrate and tributyl citrate may be included in amounts ranging up to about 30% by weight (¶ 0049-0051). Wetting agents (reads on surfactant) is disclosed on ¶ 0052. Stearyl alcohol (0.1-3%) and talc (0-50%) are also disclosed (¶ 0043-0047). Polymers such as hydroxypropyl cellulose and polyvinylpyrrolidones may be included in amounts of up to 20% by weight (¶ 0078). to [0080]). The processing of the ingredients takes place in an extruder in a temperature ranging from 120°C to 250°C (¶ 0030). In one embodiment, the mixture is processed in a twin-screw extruder, with the resulting extrudate being chopped to give pellets (¶ 0099). The molded capsules may be joined by various methods including adhesive bonding, welding by laser, ultrasound or microwaves, or by means of a snap connection (¶ 0095). In one embodiment, a capsule with a wall thickness of 0.6 mm is produced (¶ 0101). Suitable polymers disclosed include (meth)acrylate copolymers with quaternary ammonium groups and containing trimethylammoniumethyl methacrylate chloride as monomer (Eudragit® RL and/or Eudragit® RS) (¶ 0080).

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Petereit does not teach the instantly claimed amount of surfactant (of less than 2% as in claim 56); does not teach the instantly claimed amount of the lubricant stearyl alcohol (from about 10 to about 15%); does not teach absorption enhancers and does not teach a blend of hydroxypropyl cellulose polymers having a differing molecular weight.

**McAllister ('369)** teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). Also disclosed are injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012).

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof (p. 9, ¶ 0122).

More suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (p. 10, ¶ 0125). The copolymers can be used in amounts of 20% w/w or more (p. 10, ¶ 0127). Preferred polymers disclosed are Eudragit®RL 100. A suggested blend of

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polymers would be the combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0131).

Water soluble and water-insoluble polymers are discussed at p. 10, ¶ 0136-0137.

The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (p. 11, ¶ 0142). Specific substances are disclosed at page 11, (p. 11, ¶ 0143 - p. 12 ¶ 0156). These substances (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) are the same as those claimed by Applicant. Lubricants are disclosed in amounts of from about 0 to about 30% w/w (p. 12, ¶ 0154). Surfactants are provided in amounts of from 0 to about 10% and include sodium dodecyl sulphate or block copolymers of ethylene oxide and propylene oxide (¶ 0143 & 0144). Absorption enhancers such as lecithin, sucrose fatty acid esters, Vitamin E-TPGS are also disclosed (p. 11, ¶ 0142-0143). Blends of hydroxypropyl cellulose polymers having differing molecular weight are disclosed at p. 12, ¶ 0150 and include KLUCEL. Suitable amounts of dissolution modifying agents (i.e., disintegrants) are about 10% to 40% as well as 10% to 70% for swellable solids such as hydroxypropylcellulose (p. 12, ¶ 0152). In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Moreover, with regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration

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will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specific ranges/amounts of surfactant and lubricant, the absorption enhancers and blends of hydroxypropyl cellulose polymers as taught by McCallister within the formulations of Petereit. One would do so with a reasonable expectation of success because McCallister teaches the use of processing agents, excipients and additives (i.e., surfactants, lubricants, absorption enhancers) in beneficially-effective amounts and ranges and further teaches blends of hydroxypropylcellulose polymers (i.e., KLUCEL) which are utilized for their dissolution modifying effects. The expected result would be an improved process for formulating injection molded compositions. Thus, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art, given the combined teachings of Petereit and McCallister (‘369).

\* \* \* \* \*

**Claims 47-64, 69-77, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit *et al* (hereinafter “Petereit”) (U.S. Pat. Appln. Pubn. No. 2002/0160042) in view of McAllister *et al*. (hereinafter “McAllister”) (U.S. Pat. Appln. Pubn. No. 2003/0049311).**

**Petereit (‘042)** teaches a process for producing moldings by injection-molding and injection-molded capsules made thereby, which comprise methacrylate copolymers composed of



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from 50% to 70% by weight of methyl acrylate, 10 to 30% by weight of methyl methacrylate, and 5% to 15% by weight of methacrylic acid (see abstract, ¶ 0005-0030 & 0038 & Example 1). The capsule may include other components, such as a release agent, a plasticizer, additives or auxiliaries, pharmaceutical agents, and other polymers or copolymers (see abstract). Plasticizers such as triethyl citrate and tributyl citrate may be included in amounts ranging up to about 30% by weight (¶ 0049-0051). Wetting agents (reads on surfactant) is disclosed on ¶ 0052. Stearyl alcohol (0.1-3%) and talc (0-50%) are also disclosed (¶ 0043-0047). Polymers such as hydroxypropyl cellulose and polyvinylpyrrolidones may be included in amounts of up to 20% by weight (¶ 0078). to [0080]). The processing of the ingredients takes place in an extruder in a temperature ranging from 120°C to 250°C (¶ 0030). In one embodiment, the mixture is processed in a twin-screw extruder, with the resulting extrudate being chopped to give pellets (¶ 0099). The molded capsules may be joined by various methods including adhesive bonding, welding by laser, ultrasound or microwaves, or by means of a snap connection (¶ 0095). In one embodiment, a capsule with a wall thickness of 0.6 mm is produced (¶ 0101). Suitable polymers disclosed include (meth)acrylate copolymers with quaternary ammonium groups and containing trimethylammoniummethyl methacrylate chloride as monomer (Eudragit® RL and/or Eudragit® RS) (¶ 0080).

Petereit does not teach the instantly claimed amount of surfactant (of less than 2% as in claim 56); does not teach the instantly claimed amount of the lubricant stearyl alcohol (from about 10 to about 15%) and does not teach absorption enhancers.

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**McAllister ('311)** teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). Also disclosed are injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012).

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof (p. 9, ¶ 0120).

More suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (p. 10, ¶ 0123). The copolymers can be used in amounts of 20% w/w or more (p. 10, ¶ 0125). Preferred polymers disclosed are Eudragit®RL 100. A suggested blend of polymers would be the combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0130).

Water soluble and water-insoluble polymers are discussed at p. 10, ¶ 0135-0136.

The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the

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like (p. 11, ¶ 0141). Specific substances are disclosed at page 11, (p. 11, ¶ 0143 – p. 12 ¶ 0160). These substances (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) are the same as those claimed by Applicant. Lubricants are disclosed in amounts of from about 0 to about 30% w/w (p. 12, ¶ 0155). Surfactants are provided in amounts of from 0 to about 10% and include sodium dodecyl sulphate or block copolymers of ethylene oxide and propylene oxide (¶ 0143 & 0144). Absorption enhancers such as lecithin, sucrose fatty acid esters, Vitamin E-TPGS are also disclosed (p. 11, ¶ 0141-0143). Dissolution modifying agents can comprise hydroxypropylmethyl cellulose and other hydroxyalkyl cellulose derivatives p. 11, ¶ 0146-0147. Suitable amounts of dissolution modifying agents (i.e., disintegrants, swellable solids) are from about 2.5% to 70% w/w (p. 11, ¶ 0146). In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

With regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specific ranges/amounts of surfactant and lubricant and the absorption enhancers as taught by McCallister ('311) within the formulations of Petereit. One would do so with a reasonable expectation of success because McCallister teaches the use of processing agents, excipients and additives (i.e., surfactants, lubricants, absorption enhancers) in beneficially-effective amounts which are utilized for their superior material-effecting capabilities. The expected result would be an improved process for formulating injection molded compositions. Thus, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art, given the combined teachings of Petereit and McCallister ('311).

\* \* \* \* \*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 47-84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/470,438 ('438 Application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '438 application also claims a process for making a pharmaceutical dosage form comprising steps that include introducing and combining methacrylate copolymers with an excipient composition, comprised of a lubricant, dissolution modifying excipient and optionally, surfactant and placing into an elongated hot melt extruder, followed by mixing said copolymer with excipient composition, forming a homogeneous composition and ejecting the homogeneous composition in the form of a strand, cutting the strand into pellets and introducing said pellets into an injection molder and forming subunits of a thin-walled capsule compartments, or a solid matrix subunits from said pellets by injection molding (see claim 56 of '438). The '438 application also claims the same lubricants, surfactants and dissolution modifying agents as the instant application. See claims 57-59 of '438.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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(2) Claims 47-84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-61 of copending Application No. 10/470,439 ('439 Application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '439 application also claims a process for making a pharmaceutical dosage form comprising steps that include introducing and combining an Aminoalkyl Methacrylate Copolymer E with an excipient composition, comprised of at least one dissolution modifying excipient and optionally a second dissolution modifying excipient selected from a swellable solid, disintegrant, non-reducing sugar, water-soluble filler, wicking agent and inorganic salt and optionally a plasticizer and placing into an elongated hot melt extruder, followed by mixing said Aminoalkyl Methacrylate Copolymer E with excipient composition, forming a homogeneous composition and extruding the homogeneous composition in the form of a strand, cutting the strand into pellets and introducing said pellets into an injection molder and forming a thin-walled capsule shell compartments (see claim 47 of '439). The '439 application also claims the same lubricants and dissolution modifying agents as the instant application. See claims 48-50 of '439.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

\* \* \* \* \*

***Pertinent Art***

Prior art cited of interest by the Examiner:

**Clarke *et al.*** (U.S. Patent No. 7,163,693) (01/16/2007)

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Clarke discloses a multi-component pharmaceutical dosage form comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). Modifying agents disclosed include lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (col. 11, lines 20-36).

\* \* \* \* \*

### ***Conclusion***

--No claims are allowed at this time.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

*hns*

July 19, 2010